REMARKS

Applicants would like to thank Examiner Sajjadi for taking the time to have a telephone interview to discuss this case on April 4, 2008 with Applicants' representative Kathryn Wade. The present rejections under 35 U.S.C. § 112, first paragraph (enablement requirement) and 35 U.S.C. § 102 were discussed. Agreement was reached with respect to the § 102 rejection, and Applicants agreed to provide additional information regarding the enablement of the claimed invention.

Applicants previously canceled Claims 3, 19-30, and 32-74. Reconsideration of the present application and allowance of pending Claims 1, 2, 4-9, and 31 are respectfully requested in view of the amendments and following remarks.

Claims 10-18 were previously withdrawn as being drawn to a non-elected invention. Because the claims of the elected Group I (Claims 1-9 and 31, related to a product) are believed to be in condition for allowance, Applicants respectfully request rejoinder of Claims 10-18 (Group II, related to processes for making the product of Group I). In addition, Applicants elected the species of a trisomy of chromosome 17. As the claims are believed to be in condition for allowance as they relate to the elected species, Applicants respectfully request that the Patent Office examine the pending claims as they relate to the non-elected species at this time.

I. Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 2, 4-9, and 31 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Office Action asserted that the usefulness of the claimed abnormal karyotype ES cells is unclear and that one of skill in the art would not be able to make or use the invention without undue experimentation. Applicants respectfully traverse this rejection.

Applicants note that the claimed ES cells are particularly useful as a research tool, in place of euploid ES cells, due to the robust growth properties of the instantly claimed cells. The claimed ES cells are much easier to grow and manipulate than euploid lines, providing a distinct

advantage of the claimed ES cells over euploid cells for research. The claimed ES cells are currently available through the ATCC (ATCC Deposit No. SCRC-2002).

In addition, Applicants have entered into agreements with Invitrogen involving the claimed cells (BG01v). Under one agreement, Invitrogen is producing and selling cDNA libraries from the cell line (printout attached). The BG01v cells are particularly useful for this purpose, due to their capacity for growing large amounts of cells easily, making it much easier than if Invitrogen had been trying to work with euploid cells. Under the second agreement, Invitrogen is selling genetically modified BG01v (*i.e.*, BG01v cells containing an Oct4/GFP reporter construct)(printout attached). Further, Applicants have entered an agreement with R&D Systems, allowing R&D Systems to use the claimed cell line for internal research and development purposes.

For at least the foregoing reasons, the present specification is sufficient to enable one of ordinary skill in the art to make and use the invention without exercising undue experimentation. Therefore, the rejection under 35 U.S.C. § 112, first paragraph with respect to the enablement requirement should be withdrawn.

II. Rejections under 35 U.S.C. § 102

The Office Action rejected Claim 31 under 35 U.S.C. § 102(a) as allegedly being anticipated by Rosler *et al.* (Development Dynamics 229:259-274, 2004). In particular, the Office Action asserted that Rosler *et al.* teach human ES cells maintained in continuous culture for over one year and that 20% of individual cultures showed some degree of aneuploidy. Applicants respectfully submit that Claim 31 is novel over the teachings of Rosler *et al.*

The Office Action stated that Claim 1 was not included in this rejection because the ES cells of Claim 1 express nestin, and Rosler *et al.* do not teach ES cells that are aneuploid and that express nestin. As discussed with Examiner Sajjadi, Claim 31 also contains the limitation that the cells express nestin. Therefore, this rejection is moot with respect to Claim 31 because the claimed cells express nestin.

Rosler *et al.* do not teach each and every feature of the presently claimed invention. Therefore, Rosler *et al.* do not anticipate the present invention, and the rejection under 35 U.S.C. § 102(a) should be withdrawn.

III. Priority

The Office Action maintained that the effective filing date of the instant application is March 31, 2004, the filing date of PCT Application No. PCT/US04/10121. The Office Action alleged that the priority application (U.S. Provisional Application No. 60/459,090) fails to provide adequate support or enablement in the manner provided by 35 U.S.C. § 112, first paragraph, for one or more claims of this application. In particular, the Office Action noted that the priority application does not include Example 19 or a disclosure of the specific abnormal karyotypes in human ES cells of a specific passage number or condition. Therefore, the Office Action indicated that Claims 1, 2, 4-9, and 31 are only entitled to the priority date of March 31, 2004, the filing date of the PCT application.

Applicants respectfully submit that the currently pending claims are sufficiently supported and enabled by the disclosure in U.S. Provisional Application No. 60/459,090. The specification describes the SSEA4 selection and bulk passaging of cells with trypsin treatment at Example 6 of the provisional application, paragraphs [0142]-[0146] and Example 11, [0175]-[0178]. Undifferentiated human ES cells were selected by magnetic sorting using an anti-SSEA4 antibody and then passaged with trypsin treatment to dissociate the culture to an essentially single cell suspension, creating a cell population that expresses nestin and that inherently has the characteristic of having an abnormal karyotype. Applicants respectfully submit that one of ordinary skill in the art would expect that cells passaged in this manner and expressing nestin likely would have some chromosomal abnormality, and therefore, would have recognized that Applicants were in possession of the claimed invention at the time of filing of the provisional application. Accordingly, as the provisional application discloses this passaging technique that produces cells that express nestin and that have an abnormal karyotype, the

currently pending claims are entitled to the benefit of the priority date of the provisional application filing date.

Applicants note that even if the Patent Office maintains that the effective filing date of the instant application is March 31, 2004, Applicants believe the case still is in condition for allowance as there are no valid prior art rejections, as discussed above.

CONCLUSION

Applicants believe that the present application, as amended, is now in condition for allowance. Favorable reconsideration of the application is respectfully requested. The foregoing is submitted as a full and complete response to the Final Office Action mailed February 7, 2008.

No fees are believed due at this time. However, please charge any fees that may be due, or credit any overpayment, to Deposit Account 19-5029 (Ref. No.: 18377-0067). In addition, if there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited and encouraged to call the undersigned attorney at (404) 853-8000.

Respectfully submitted,

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